

Structured Product Labeling (SPL) OTC Sub-team Teleconference
December 13, 2010, 1:00 – 2:00 pm ET
Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

-  Huascar Batista, U.S. FDA (*guest speaker*)
-  Paule Belony, The Belong Group LLC
-  Terry Brunone, GlaxoSmithKline
-  Gail Burke, Procter & Gamble
-  Pete Carlson, Ecolab
-  Patricia Cowall-Hanover, Lilly
-  Amy Deuchler, Medline Industries, Inc.
-  Iris Feliciano, Tris Pharma
-  Lisa Fields, Blistex, Inc.
-  Chris Guay, Procter & Gamble
-  Michele Hewitt, Sandoz, Inc., Broomfield
-  Maureen Kapustynski, Cadbury
-  Ruth Kirkner, Teva
-  Mike Koenig, U.S. FDA
-  Juris Lazdins, Novartis Consumer Health, Inc.
-  Daniel Manelli, Attorney
-  Paula Markert, GlaxoSmithKline (sub-team leader)
-  LuAnn Mays, Procter & Gamble
-  Diane O'Grady, Purdue Pharma, L. P.
-  Kathy Olgers, Perrigo Company
-  Janet Riffitts, McNeil Consumer Healthcare
-  Anne Rubenfeld, Combe
-  Jennifer Seiler, Parexel Consulting
-  Howard Shatz, Data Conversion Laboratory, Inc.
-  Lonnie Smith, U.S. FDA (*guest speaker*)
-  Carl Strotz, Pfizer Consumer Healthcare
-  Beth Thompson, Medline Industries, Inc.
-  Cynthia Thompson, Kimberly-Clark Corporation
-  Leila Toubia, Combe
-  Tonya Tucker, Perrigo Company
-  Karen Vescovi, Church & Dwight Co., Inc.
-  Ann Marie Waller, Oraceutical, LLC
-  Carey Wilson, Intagras

 Barbara Wolfe, Pfizer
 Marcia Howard, CHPA staff (sub-team liaison)

II. **Next Standing Teleconference: January 10, 2011, 1:00pm ET** (unless cancelled). Standing calls for 2011 will be held on the second Monday of each month only and will be cancelled as appropriate.

III. **Discussion**

Note 1: The issues addressed during the call were **NOT** intended to imply formal FDA policy but was for discussion only. If one wishes to quote one of the invited speakers, please contact him directly for permission prior to doing so.

Note 2: The information below is a summary of the discussion and may not be all-inclusive of all comments addressed on the call. This summary does **NOT** imply FDA approval of the information provided nor reflect any direct quotes by any speaker.

- Is the import staff using the e-Listing database solely to confirm products have been drug listed or are they also still using the previous database for products that have not been required to be listed in electronic format (e.g., products for which no changes have occurred since last paper listing was submitted to the FDA)?
 - The import staff is instructed to use more than solely the e-List system. When a product arrives for importation, staff is advised to use the e-List database as well as to check the Drug Registration & Listing (DRL) database (i.e., legacy database) to determine if the listing submission has been received.
 - Both the databases are electronic so it may be useful to clarify which database industry is speaking of when speaking to import staff products at the border.
- What specific instructions or useful information can companies give to import agents who cannot locate drug listing information in the FDA database, even when the receipt for electronic submissions or copies of the paper submissions are provided? Is there a way for companies to direct the import agents to the appropriate information needed?
 - If there is a question of product listing, industry should provide a copy of the electronic submission to the agent and ask him/her to verify the product listing with both the SPL and Center contact. Products could be delayed/detained due to SPL listing issues or for other questions regarding compliance.

- Additionally, industry should contact the Division of Import Operations & Policy Regional Access Manager (RAM) to inform him/her that there is a problem and to advise that you are contacting SPL and/or Compliance about the matter. The RAM may be able to assist with resolving the problem/s.
 - Contact the district office to identify the Regional Access Manager.
 - Questions regarding validation should be directed to SPL/Data Standards Council while all compliance issues should be directed to the CDER Office of Compliance.
- If the Private Label Distributor (PLD) lists a drug and accurately identifies the Contract Manufacturer (CM), resulting in only one NDC number for the drug, does this satisfy the reporting requirements for both the PLD and the CM?
 - Under 21 CFR Part 207 and Section 510 of the Federal FD&C Act, a PLD has the option to register and list products under their own labeler code. However, the CM is still needs to register and drug list the products they make. Registration and listing are still required of the CM under Section 510 regardless of whether the product is firm is domestic or foreign.
 - PLDs can choose to list products but that doesn't absolve manufacturers from their requirements under Part 207 and Section 510 under the CFR and FD&C Act, respectively.
 - Because listing of a single product by both a PLD and manufacturer could lead to duplicate postings in DailyMed, companies were concerned about potential problems with reimbursement, duplicate files on DM, information in the PLD file not being updated when it is done by the manufacturer, and the ability to maintain confidentiality of the manufacturer.
 - Because "labeler" is the only business operation that cannot be marked as confidential, the manufacturer information would remain anonymous. The information might be assumed from the labeler code information included in the file but it would not be a direct confirmation of the information.
- There was a recommendation that FDA inform industry of the most common issues observed by the import staff in hopes of improving the information provided by companies.
- Callers were reminded of the new marketing category of "drugs for further processing" that was recently added as an option. At this time, it is unclear if products listing using this category will be included in DailyMed and/or the NDC directory.

- Batista and Smith will be invited to future calls to continue discussion of this issue and others.

IV. SPL Educational Forums/Information (*For Your Information*)

- A. **FDA SPL R4 Training Sessions** – Please visit website for updated information regarding training courses.
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml55705.htm>

- B. **FDA Training Sessions:** Monday webinars at 10:00 am ET and Q&A sessions at 11:30 am ET (same for both; cancelled for Federal holidays)

Telephone number: 1-866-775-9435

Participant passcode: 5753366

Please dial-in early as there are a limited number of ports and when they are exhausted, no one else will be able to connect to the conferences.

NOTE: FDA Technical Q&A sessions are no longer held on Wednesdays.

Please visit the SPL Wiki page to access FDA's SPL R4 eBook Training Documents (<http://spl-work-group.wikispaces.com/>)

- C. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 517342

Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to get the email information.

- D. **SPL ER/DL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)

Please email sub-team co-leaders Patricia Cowall- Hanover (COWALL-HANOVER.PATRICIA.L@LILLY.COM) or Jessica Dunn Skorupski if you want to get the email information (JSkorups@its.jnj.com).

- E. **SPL Generics Sub-team calls:** Not currently holding regular calls.
Please email sub-team leader Virginia Hogan if you want to get the email information (Virginia.Hogan@tevausa.com).
- F. **Medical Products Sub-team calls:** Every other Thursday at 10:30 am EST
Please email Sub-team leader Myron Finseth
(myron.finseth@medtronic.com) if you want to join this sub-team.

Telephone Number: 770-657-9270

Participant passcode: 745896

Please separate attachment for additional information.

- G. **SPL Usage Discussion Group**
Please email or call Terry Brunone (Theresa.M.Brunone@gsk.com; +1-215-751-3210) or Gary Saner (gsaner@reedtech.com; +1-610-731-7192) if you wish to join the discussion group.

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